IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY *Plaintiff*,	)	
v.	)	Civil Action No. 4:21-cv-01058-P
UNITED STATES FOOD AND DRUG ADMINISTRATION, *Defendant*.	)	

DEFENDANT'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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I. SUMMARY

Plaintiff Public Health and Medical Professionals for Transparency filed this suit pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, seeking certain records from the U.S. Food and Drug Administration ("FDA" or "the agency"), relating to "the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty . . . for individuals 16 years of age and older." *See* Compl., ECF No. 1; Pl.'s FOIA Request, ECF No. 1-1 at 1. FDA processed a total of 1,200,874 pages of responsive records in response to Plaintiff's FOIA Request, completing production of all responsive, non-exempt information by November 1, 2023 and spending more than $3.5 million to do so. The parties have narrowed the issues in dispute to only the adequacy of FDA's search. *See* Oct. 1, 2024 Ltr. from E. Brehm, ECF No. 87 ("waiv[ing] the right to challenge the redactions and withholdings in the production to date"). Because FDA conducted a reasonable and adequate search for responsive records, FDA is entitled to summary judgment in its favor.

II. BACKGROUND

A. Regulatory Framework

1. Biological Product Licensing Process

Vaccines are biological products that are regulated under the Public Health Service Act ("PHSA"), 42 U.S.C. § 262(i)(1), as well as "drugs" regulated under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(g)(1)(B). Vaccines are approved for marketing through applications known as Biologics License Applications ("BLA"). *See* 42 U.S.C. § 262(a). A vaccine that is subject to an approved BLA is not required to have an approved new drug application under 21 U.S.C. § 355. *See* 42 U.S.C. § 262(j).

A sponsor of a biological product—such as a vaccine—generally begins the process of studying an investigational product by performing a variety of laboratory tests on it, including certain safety tests in animals. Declaration of Suzann Burk ("Burk Decl.") ¶ 7 (App'x 002); *see*

also 21 C.F.R. Part 58. The sponsor's focus at this stage is to collect the data and information necessary to establish that the investigational product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. Burk Decl. ¶ 7 (App'x 002) However, before the investigational biological product may be administered to human subjects, the sponsor must first submit an investigational new drug application ("IND") to FDA. *See* 21 C.F.R § 312.20; *see generally* 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3); 21 C.F.R. Part 312.

In general, an IND application contains the results of the laboratory and animal tests (referred to as pre-clinical data) that have been performed, gathered, and submitted by the sponsor; manufacturing information for the investigational biological product; and proposals (known as protocols) describing the sponsor's plans for testing the investigational biological product in human subjects. *See generally* 21 C.F.R. § 312.23; *see also* Burk Decl. ¶ 8 (App'x 003). Tests conducted in human beings are called clinical trials, and FDA medical and scientific reviewers evaluate the data submitted in the IND, including the proposed clinical trial protocols. Burk Decl. ¶ 8 (App'x 003). If the reviewers determine, from the evidence, that the biological product does not pose an unreasonable or significant risk of illness or injury to human subjects and if there are no other problems with the submission that cause the agency to identify the need for a clinical hold, the agency will not bar the clinical trial from proceeding. *Id.* (App'x 003). Given that an IND is submitted during the investigational stage of drug development, IND files may contain data and information regarding formulations, dosages, or uses that differ from those that are ultimately licensed. *Id.* (App'x 003).

In a subsequent stage of the development process, sponsors may submit to FDA a formal application for licensing (*i.e.*, marketing approval), which is called a BLA. *See* 42 U.S.C. § 262(a)(1)(A); *see also* Burk Decl. ¶ 9 (App'x 003). BLAs include various information and data,

including nonclinical and clinical data; information about manufacturing methods and locations; data establishing stability of the product through the dating period; summaries of results from tests performed on the lots of representative samples of the product; and, among other things, mockups of the labels, enclosures, medication guide if proposed, and containers as applicable. *See* 21 C.F.R. § 601.2(a); *see also* Burk Decl. ¶ 9 (App'x 003).

Pursuant to the PHSA, FDA approves a BLA on the basis of a demonstration that (1) the vaccine is "safe, pure, and potent," and (2) the facility in which the vaccine is produced meets standards designed to assure that the vaccine continues to be safe, pure, and potent. 42 U.S.C. § 262(a)(2)(C)(i). The applicant must also consent to inspection of the manufacturing facility. *Id.* § 262(a)(2)(C)(ii). If FDA determines that the BLA meets the statutory and regulatory requirements, FDA will issue a biologics license for the product, authorizing the sponsor of that particular BLA to market that new product. *See* 21 C.F.R. § 601.4(a).

IND and BLA files continue to be maintained following initial licensure of a product, and sponsors may continue to make submissions to the relevant file. Burk Decl. ¶ 11 (App'x 004). For example, clinical trial data for formulations, dosages, or uses that differ from the licensed vaccine could be submitted to the IND file; and certain post-licensure submissions for the licensed vaccine (such as narrative periodic reports) would be submitted to the BLA file. *Id.* (App'x 004).

2. Confidentiality of Biological Product Licensing Files

FDA has promulgated regulations that—along with other relevant statutes and regulations relating to disclosure of records, including FOIA—govern the availability of data and information in IND and BLA files. *See* 21 C.F.R. §§ 312.130(b), 601.50, 601.51.

Under 21 C.F.R. § 601.50, "[t]he existence of an IND notice for a biological product will not be disclosed by [FDA] unless it has previously been publicly disclosed or acknowledged," and

"[t]he availability for public disclosure of all data and information in an IND file for a biological product shall be handled in accordance with the provisions established in § 601.51." 21 C.F.R. § 601.50.

Section 601.51 is titled "Confidentiality of data and information in applications for biologics licenses." 21 C.F.R. § 601.51. It defines, for the purposes of that regulation, the term "biological product file" ("BPF") to include "all data and information submitted with or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related submissions." *Id.* § 601.51(a). Section 601.51 also provides that, unless a BPF has previously been disclosed or acknowledged, FDA cannot disclose its existence or any data or information therein before a BLA has been approved. *Id.* § 601.51(b)-(c).[1]

Once a biologics license has been issued, certain data in the BPF is available for public disclosure upon receipt of a FOIA request. *See, e.g.*, 21 C.F.R. § 601.51(e); *see also id.* § 20.20; *id.* § 20.23. Specifically, Section 601.51(e) lists certain "data and information in the biological product file" that are "immediately available for public disclosure" following licensure, "unless extraordinary circumstances are shown." *Id.* § 601.51(e).[2] Section 601.51(e) is not a list of items

[1] If the existence of a BPF has been publicly disclosed or acknowledged before a license has been issued, then FDA generally still cannot make information and data in the file available for disclosure until a license has been issued. *See* 21 C.F.R. § 601.51(d).

[2] The categories of data and information listed in Section 601.51(e) include: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 20.61 of this chapter. (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in § 20.81 of this chapter. (5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and it is shown to fall within the exemption established in § 20.61 of this chapter. (6) All correspondence and written summaries of oral discussions relating to the biological

that must be in a BPF, but rather describes information that, if found in a BPF, may generally be disclosed absent extraordinary circumstances. Burk Decl. ¶ 16 (App'x 005–006). In turn, Section 601.51(f) lists the types of data and information that, if found in a BPF, generally cannot be publicly disclosed even after a biological product is licensed. *See* 21 C.F.R. § 601.51(f).

B. Procedural History

On August 27, 2021, Plaintiff submitted a FOIA Request to FDA seeking: "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." *See* Pl.'s FOIA Request, ECF No. 1-1 at 1. Plaintiff's FOIA Request further clarified that (a) "Pfizer Vaccine" meant "the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty . . . for individuals 16 years of age and older" and (b) its Request "includ[ed] but [was] not limited to all data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)." *Id.* at 1 & n.2.

FDA assigned Plaintiff's FOIA Request the control number 2021-5683. Burk Decl. ¶ 18 (App'x 006). On September 9, 2021, FDA denied Plaintiff's request for expedited processing. *See* Sept. 9, 2021 Ltr. from FDA to PHMPT, ECF No. 1-4. Plaintiff's FOIA Request then entered FDA's Access Litigation and Freedom of Information Branch's ("ALFOI")[3] complex queue for processing. Burk. Decl. ¶ 19 (App'x 006); *see Open Am. v. Watergate Special Prosecution Force*,

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product file, in accordance with the provisions of part 20 of this chapter. (7) All records showing the manufacturer's testing of a particular lot, . . . manufacturing procedures and controls, yield from raw materials, costs, or other material falling within § 20.61 of this chapter. [and] (8) All records showing the testing of and action on a particular lot by the Food and Drug Administration."

[3] ALFOI is one of three branches of the Division of Disclosure and Oversight Management ("DDOM"), in the FDA's Center for Biologics Evaluation and Research ("CBER"). *See* Burk Decl. ¶ 4 (App'x 002). ALFOI is primarily responsible for the review and disclosure of CBER-maintained records in response to FOIA requests. *Id.* (App'x 002).

547 F.2d 605, 616 (D.C. Cir. 1976) ("The good faith effort and due diligence of the agency to comply with all lawful demands under the Freedom of Information Act in as short a time as is possible by assigning all requests on a first-in, first-out basis, except those where exceptional need or urgency is shown, is compliance with the Act.").

On September 16, 2021, before Plaintiff's Request came up in the queue, Plaintiff filed this lawsuit. *See* Compl., ECF No. 1. Defendant filed its answer on October 18, 2021. *See* Answer, ECF No. 14. Between November 17, 2021, and January 31, 2022, ALFOI produced 13,727 pages of responsive records to Plaintiff that Plaintiff had identified as "priority" records. Burk Decl. ¶ 22 (App'x 006–007). On January 6, 2022, this Court ordered a processing schedule of 55,000 pages every thirty days. *See* Jan. 6, 2022 Order, ECF No. 35. On February 2, 2022, upon consideration of the agency's motion to partially modify the January Order to "stand up" unprecedented and extraordinary operations to comply with the Order, the Court allowed for a graduated processing schedule, which required the agency to process 10,000 pages per month in March and April 2022; 80,000 pages per month in May, June, and July 2022; 70,000 pages in August 2022; and 55,000 pages per month thereafter. *See* Feb. 2, 2022 Order, ECF No. 56 ("February 2, 2022 Order"). To the extent the agency processed more than the required page count in any month, the Court permitted the agency to "bank" the extra pages and apply them to a later month toward its quota for that month. *Id.* Pursuant to the Court's February 2, 2022 Order, ALFOI processed 1,187,147 pages of responsive records over the course of twenty-one months and spent more than $3.5 million through October 2023 to do so.[4] Burk Decl. ¶ 24 (App'x 007). Combined

[4] Following the Court's February 2022 Order and the Court's June 12, 2023 production order in *PHMPT v. FDA*, 22-cv-915 (N.D. Tex.) ("*PHMPT 2*") (requiring FDA to process across the two cases at least 90,000 to 110,000 pages per month from July 2023 through November 2023 and, starting in December 2023, in *PHMPT* 2, at least 180,000 pages per month until June 2025), FDA

with the 13,727 pages of records produced prior to the Court's February 2, 2022 Order, FDA processed a total of 1,200,874 pages of responsive records in response to Plaintiff's FOIA Request. *Id.* ¶ 25 (App'x 007).

On October 1, 2024, Plaintiff filed a letter with the Court, "waiv[ing] the right to challenge the redactions and withholdings in the production to date." Oct. 1, 2024 Ltr. from E. Brehm, ECF No. 87.[5] Thus, the only issue remaining for resolution by summary judgment in this case is the adequacy of the agency's search.

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has sought stays in other FOIA litigations, citing the voluminous production requirements in both PHMPT cases. To date, 7 stays have been granted, and 3 stay requests are awaiting decisions. *See Wright v. U.S. Dep't of Health & Hum. Servs.*, No. 22-cv-1378 (RC), ECF No. 28 (D.D.C.); *Children's Health Defense v. FDA*, No. 23-cv-2316 (LLA) (D.D.C.) (Dec. 13, 2023 and July 18, 2024 Minute Orders); *Informed Consent Action Network v. FDA*, No. 23-cv-0219 (RBW), ECF Nos. 27 & 29 (D.D.C.); *Children's Health Def. v. FDA*, No. 23-cv-0220 (RDM), ECF No. 25 (D.D.C.) (request to extend stay pending); *Children's Health Defense v. Ctrs. for Disease Control & Prevention*, No. 23-cv-0431 (TNM), ECF No. 28 (D.D.C.); *Informed Consent Action Network v. FDA*, No. 23-3675 (JMC) (D.D.C.) (Sept. 4, 2024 Minute Order); *Informed Consent Action Network v. FDA*, No. 23-3282 (ABJ), ECF No. 23 (D.D.C.); *John Solomon v. U.S. Dep't of Health & Hum. Servs.*, No. 24-0572 (RBW), ECF No. 10 (D.D.C.) (motion for stay filed June 20, 2024); *Informed Consent Action Network v. FDA*, No. 24-1555 (RCL), ECF No. 13 (D.D.C.) (motion for stay filed Sept. 25, 2024); and *Informed Consent Action Network v. FDA*, No. 24-1761 (CJN), ECF No. 13 (D.D.C.) (motion for stay filed Sept. 27, 2024).

[5] Plaintiff's October 1, 2024 letter purports to preserve the right of "individual member(s) of PHMPT [who] wish[] to challenge a redacted or withheld document from this production" to "submit a new FOIA request with FDA on his or her behalf (as opposed to on behalf of PHMPT)," "go through the normal administrative course to attempt to obtain the document without any redactions," and to potentially "litigate to challenge the redactions or withholdings in a separate litigation from the instant litigation." Oct. 1, 2024 Ltr. from E. Brehm, ECF No. 87. While not relevant to the issues presented in this summary judgment motion, FDA does not concede that "individual member(s) of PHMPT" would have standing for such a challenge. FDA reserves the right to process any future FOIA requests according to its normal processes and to assert any legal or equitable defenses that it determines at the time are applicable, including, for example, on the basis that the requester is estopped from pursuing information/claims that were waived in the instant litigation and arguments with respect to standing. *See* Oct. 15, 2024 Joint Status Report at 2 n.1, ECF No. 88.

III. LEGAL STANDARDS

"[M]ost FOIA cases are resolved at the summary judgment stage." *Flightsafety Servs. Corp. v. Dep't of Labor*, 326 F.3d 607, 610 (5th Cir. 2003); *see also Brayton v. Office of the U.S. Trade Representative*, 641 F.3d 521, 527 (D.C. Cir. 2011) (observing that "the vast majority of FOIA cases can be resolved on summary judgment").[6] Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In responding to the summary judgment motion, the non-movant attempting to show that a fact is genuinely disputed must "cit[e] to particular parts of materials in the record," or show that the materials cited by the movant do not establish the absence of a genuine dispute. *See* Fed. R. Civ. P. 56(c)(1).

To be entitled to summary judgment, "the agency must establish that its search for the requested material [was] adequate . . . ." *Highland Cap. Mgmt., LP v. IRS*, 408 F. Supp. 3d 789, 800–01 (N.D. Tex. 2019) (citing *Driggers v. United States*, No. 3:11-cv-229, 2011 WL 5525337, at *3 (N.D. Tex. 2011)); *see also Light v. Dep't of Justice*, 968 F. Supp. 2d 11, 23 (D.D.C. 2013). In general, a court's decision on a summary judgment motion in FOIA cases "does not hinge on the existence of a genuine issue of material fact," and is instead based on the sufficiency of the agency declaration. *See Hemenway v. Hughes*, 601 F. Supp. 1002, 1004 (D.D.C. 1985). A court may grant summary judgment "on the basis of agency affidavits if they contain reasonable specificity of detail rather than merely conclusory statements, and if they are not called into question by contradictory evidence in the record or by evidence of agency bad faith." *Aguiar v. DEA*, 865 F.3d 730, 734–35 (D.C. Cir. 2017) (citation omitted).

[6] Courts in the Fifth Circuit frequently rely on FOIA precedent from the D.C. Circuit, "the federal appellate court with the most experience in the field." *Cooper Cameron Corp. v. U.S. Dep't of Labor*, 280 F.3d 539, 543 (5th Cir. 2002).

IV. ARGUMENT AND AUTHORITIES

A. Standards Governing an Adequate Search

An agency is entitled to summary judgment in a FOIA case with respect to adequacy of its search if the agency shows "that it made a good faith effort to conduct a search for the requested records, using methods which can be reasonably expected to produce the information requested." *Oglesby v. U.S. Dep't of Army*, 920 F.2d 57, 68 (D.C. Cir. 1990) (citations omitted), *superseded by statute on other grounds by* Electronic FOIA Amendments of 1996, Pub. L. No. 104-231, 110 Stat. 3048; *see also Batton v. Evers*, 598 F.3d 169, 176 (5th Cir. 2010) (citing *Oglesby*). This is "a standard of reasonableness." *Davis v. DOJ*, 460 F.3d 92, 105 (D.C. Cir. 2006) (citation omitted); *see also Verde v. FAA*, 287 F. Supp. 3d 661, 667 (S.D. Tex. 2018) ("The adequacy of an agency's search is measured by a standard of reasonableness and is dependent upon the circumstances of the case." (quoting *Weisberg v. U.S. Dep't of Justice*, 705 F.2d 1344, 1351 (D.C. Cir. 1983))). "The issue is *not* whether other documents may exist, but rather whether the search for undisclosed documents was adequate." *Batton*, 598 F.3d at 176 (quoting *In re Wade*, 969 F.2d 241, 249 n.11 (7th Cir. 1992)); *see also Judicial Watch, Inc. v. Rossotti*, 285 F. Supp. 2d 17, 26 (D.D.C. 2003) ("Perfection is not the standard by which the reasonableness of a FOIA search is measured.").

An agency may establish the reasonableness of its search by "reasonably detailed, nonconclusory affidavits describing its efforts." *Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F.3d 312, 318 (D.C. Cir. 2006). "Agency affidavits are accorded a presumption of good faith, which cannot be rebutted by 'purely speculative claims about the existence and discoverability of other documents.'" *SafeCard Servs., Inc. v. SEC*, 926 F.2d 1197, 1200 (D.C. Cir. 1991); *see also Batton*, 598 F.3d at 176 ("[I]n analyzing the affidavits and declarations submitted by the government, the agency is entitled to a 'presumption of legitimacy' unless there

is evidence of bad faith in handling the FOIA request.").

Because FOIA requires "both systemic and case-specific exercises of discretion and administrative judgment and expertise," it "is hardly an area in which the courts should attempt to micro manage the executive branch." *Schrecker v. DOJ*, 349 F.3d 657, 662 (D.C. Cir. 2003) (citation omitted). Thus, when using its administrative judgment and expertise to conduct a search, "a federal agency has discretion in crafting a list of search terms that they believe to be reasonably tailored to uncover documents responsive to the FOIA request," and "it is not within the reviewing court's province to nitpick the agency's selection of search terms." *Muckrock, LLC v. CIA*, 300 F. Supp. 3d 108, 125 (D.D.C. 2018) (internal quotation marks omitted). Moreover, "[t]here is no requirement that an agency search every record system." *Batton*, 598 F.3d at 176 (quoting *Oglesby*, 920 F.2d at 68). Agencies are also "not required to . . . perform searches that are not compatible with their own document retrieval systems." *See Leopold v. U.S. Dep't of Justice*, 301 F. Supp. 3d 13, 23 (D.D.C. 2018) (internal quotation marks omitted).

"FOIA requires agencies to search for records only as of a specific cut-off date." *Hardaway v. CIA*, 456 F. Supp. 3d 51, 60 (D.D.C. 2020) (citing *Kissinger v. Reporters Comm. For Freedom of the Press*, 445 U.S. 136, 152 (1980)). Courts have "repeatedly held that a date-of-*search* cut-off is reasonable." *Id.* (emphasis in original); *see also Edmonds Inst. v. U.S. Dep't of Interior*, 383 F. Supp.2d 105, 111 (D.D.C. 2005) ("The D.C. Circuit has all but endorsed the use of date-of-search as the cut-off date for FOIA requests" (citing *Public Citizen v. Dep't of State*, 276 F.3d 634, 642 (D.C. Cir. 2002))).

Applying these principles, the FDA is entitled to summary judgment with respect to the adequacy of its search.

B. FDA Conducted a Reasonable Search Designed to Discover All Records Responsive to the FOIA Request

FDA's search was "reasonably calculated to uncover all relevant documents." *Weisberg*, 705 F.2d at 1351; *see Batton*, 598 F.3d at 176. The accompanying declaration of Suzann Burk, the Director of the Division of Disclosure and Oversight Management, Office of Communication Outreach and Development in FDA's Center for Biologics Evaluation and Research, recounts FDA's search in detail. *See generally* Burk Decl. (App'x 001–017).

In an effort to provide Plaintiff with the greatest scope of data and information that the literal language of its FOIA Request could support, the agency searched for and processed the entire BPF for the Pfizer-BioNTech Comirnaty vaccine approved for individuals 16 years of age and older ("original Comirnaty vaccine licensure") through October 27, 2021—which was the date the agency began its search. *Id.* ¶ 26 (App'x 008); *see also Miller v. Casey*, 730 F.2d 773, 777 (D.C. Cir. 1984) (an agency is "bound to read [the request] as drafted, not as either agency officials or [the requestor] might wish it was drafted"); *Campbell v. Dep't of Justice*, 164 F.3d 20, 28 (D.C. Cir. 1998) ("FOIA demands only a reasonable search tailored to the nature of a particular request.").

Under 21 C.F.R. § 601.51(a), the BPF is composed of "all data and information submitted with or incorporated by reference in [the BLA], IND's incorporated into any such application, master files, and other related submissions." 21 C.F.R. § 601.51(a). In accordance with that regulation, as discussed below, the agency conducted an expansive search across multiple, independent filing systems for the following categories of records related to the original Comirnaty vaccine licensure, through the search cut-off date of October 27, 2021: (1) records submitted by Pfizer to the BLA prior to licensure; (2) records submitted by Pfizer to the BLA following licensure; (3) FDA-generated records routinely prepared and filed during review of

BLA submissions; (4) IND records incorporated into the BLA; (5) master file records referenced in the BLA; (6) other records incorporated by reference into the BLA; and (7) other related submissions for the original licensure (Biological Product Deviation Reports, certain lot release materials, and lot distribution reports). Burk Decl. ¶ 27 (App'x 008–009).

1. Biologics License Application Submissions

The bulk of the BPF is the BLA. *Id.* ¶ 28 (App'x 009). FDA searched for and processed all of Pfizer's submissions to the BLA through October 27, 2021 (the search cut-off date). *See id.* ¶¶ 29, 31 (App'x 009–010). BLA submissions are tracked by an FDA database called Regulatory Management System-Biologics Licensing Application (RMS-BLA), which assigns each BLA a unique submission tracking number ("STN"). *Id.* ¶ 29 (App'x 009). The STN for Pfizer's BLA for the original Comirnaty vaccine licensure is 125742. *Id.* (App'x 009). BLA submissions are downloadable from an FDA database called Lorenz docuBridge. *Id.* (App'x 009). FDA reviewed Lorenz docuBridge for STN 125742 and determined that Pfizer had made 77 submissions to STN 125742/0: 2 containing the original BLA application (STN 125742/0/0 and STN 125742/0/1) and 75 subsequent BLA amendment submissions up until the date of licensure. *Id.* (App'x 009). The agency also found that between licensure and the October 27, 2021 search cut-off date, Pfizer made additional submissions to STN 125742, and, upon subsequent review, the agency determined that 26 such submissions were responsive (post-marketing commitment/requirements ("PMC/Rs"), product correspondence, labeling and promotional material, and narrative periodic safety reports submitted to the BLA and related to the original Comirnaty vaccine licensure). *Id.* (App'x 009–010). BLAs are organized by subject matter into five "Modules," and the BLA submissions discussed above consisted of various Module 1–5 records, including but not limited to individual Case Report Forms—which are submitted for deaths, other serious adverse events,

and withdrawals from a study due to adverse events, or as additionally requested by FDA—and clinical data files. *See id.* ¶¶ 28, 30 (App'x 009–010).

Overall, as discussed above, the agency processed the 77 pre-licensure submissions and the 26 post-licensure submissions (103 total submissions) in response to Plaintiff's FOIA Request. *Id.* ¶ 31 (App'x 010). These records totaled approximately 1,079,089 pages. *Id.* (App'x 010).

2. FDA-Generated Records

FDA further searched for and processed the records routinely prepared and filed by the agency during its review of the aforementioned 103 BLA submissions, including, among other things, memoranda of teleconferences between FDA and Pfizer, agency review memoranda evaluating the BLA submissions, agency information requests to Pfizer, and inspection records. *Id.* ¶ 32 (App'x 010). Using CBERConnect—a centralized database of agency-generated records related to the licensing process—the agency searched for STN 125742 and identified (i) 135 records generated by FDA in response to, or in conjunction with, Pfizer's 77 BLA submissions prior to licensure, and (ii) 11 records generated by FDA in response to, or in conjunction with, Pfizer's 26 BLA submissions post-licensure (through the October 27, 2021 search cut-off date). *Id.* (App'x 010). FDA processed those 146 FDA-generated records. *Id.* ¶ 33 (App'x 011).

3. Investigational New Drug Application Records Incorporated into the BLA

The agency searched for and processed all IND submissions incorporated into the 103 BLA submissions by Pfizer and the 146 FDA-generated records. IND submissions are tracked by an FDA database called Biologics Investigational and Related Applications Management System ("BIRAMS"), which assigns each IND a submission tracking number (called an "Investigational and Related Applications (IRA) number"). *Id.* ¶ 34 (App'x 011). The IRA number associated with the original Comirnaty vaccine is 19736. *Id.* (App'x 011).

Because it is standard practice for the sponsor and FDA reviewer to refer to IND records by IRA number, the agency searched for "19736" across the 103 BLA submissions and identified 51 records referenced by tracking number or description/date that were incorporated into the original Comirnaty vaccine licensure. *Id.* ¶ 35 (App'x 011). FDA also searched for "19736" across the above-discussed 146 FDA-generated records to determine whether there were any additional identifiable portions of IND 19736 incorporated into the BLA, and identified an additional 279 IND records from that review. *Id.* ¶ 36 (App'x 011). Thus, overall, the agency processed 330 IND records in response to Plaintiff's FOIA Request. *Id.* ¶ 37 (App'x 011).

4. Drug Master Files

FDA also searched for and processed all master files referenced by Pfizer in the BLA. A drug master file ("DMF") is a submission to FDA that provides confidential, detailed information about, among other things, the facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drugs. *Id.* ¶ 38 (App'x 011). The purpose of a DMF is to allow the proprietary information therein to be incorporated by reference by sponsors of products seeking approval or licensure for FDA's consideration during review of the sponsor's application, without the owner of the master file having to disclose the information in the master file. *Id.* (App'x 011–012). While sponsors of a biological product obtain a right of reference to the DMF through the DMF holder's Letter of Authorization, the information in the DMF itself is not disclosed to the sponsor. *Id.* (App'x 012).

The agency looked at subfolder 1.4.2 (the "Statement of right of reference") of the BLA for STN 125742 to identify the DMFs to which Pfizer had obtained a right of reference. *Id.* ¶ 39 (App'x 012). The submission for that subfolder identified eight letters of authorization for eight DMFs—each of which were related to packaging materials, specifically glass vials and stoppers.

Id. (App'x 012). These eight DMFs were maintained by FDA's Center for Drug Evaluation and Research ("CDER"). *Id.* ¶ 40 (App'x 013). ALFOI contacted CDER's Division of Information Disclosure Policy to request their assistance in retrieving the DMFs. *Id.* (App'x 013). All but one of the eight DMFs was in paper format and archived at an off-site records storage facility. *Id.* (App'x 013). After all eight DMFs were retrieved, CDER processed them in response to Plaintiff's FOIA Request. *Id.* ¶ 41 (App'x 013)

5. Other Records Incorporated by Reference

The agency also reviewed the BLA records for references to records in the emergency use authorization ("EUA") file for the COVID-19 vaccine for individuals 16 years of age and older, which had been authorized prior to Pfizer's submission of its BLA. *Id.* ¶ 42 (App'x 013). The agency tracks EUA records in BIRAMS, and the IRA number associated with Pfizer's COVID-19 vaccine EUA file is 27034. *Id.* (App'x 013). Because it is standard practice for the sponsor and FDA reviewer to refer to EUA records by IRA number, the agency searched for "27034" across the 103 BLA submissions and 146 FDA-generated records and determined that the 44 references did not incorporate by reference any EUA-file records. *Id.* (App'x 013). Instead, the references were "mis-hits" (*e.g.*, reflecting a portion of a clinical trial participant identification number), were for background or informational purposes only (*i.e.*, they did not incorporate by reference a specific EUA record), or were duplicative of BLA submissions or IND submissions already processed in response to Plaintiff's FOIA Request. *Id.* (App'x 013).

In addition, during the course of its review of BLA records, the agency identified that Pfizer had made a submission called a summary monthly safety report ("SMSR") to the BLA that Pfizer called SMSR #10. *Id.* ¶ 43 (App'x 013). The agency searched for and located SMSR #'s 1–9 and accompanying submission records (which were all found in IND 19736), and FDA-

generated records reflecting review of these SMSRs (found through CBERConnect) and processed them. *Id.* (App'x 013–014).

6. Biological Product Deviation Reports

The agency's search also included attempts to locate any Biological Product Deviation Reports ("BPDRs") related to the original Comirnaty vaccine licensure. *Id.* ¶ 44 (App'x 014). BPDRs are reports by manufacturers of changes or unexpected events that occur during manufacturing that have the potential to affect the safety, purity, or potency of the biological product. *Id.* (App'x 014).

BDPRs are accessible through the CBER Error and Accident Reporting System ("CEARS"), which is utilized by CBER's Program Surveillance Branch in its Division of Inspections and Surveillance in the Office of Compliance and Biologics Quality ("OCBQ"). *Id.* ¶ 45 (App'x 014). ALFOI contacted the Program Surveillance Branch and asked for any BPDRs submitted for [the] Pfizer Comirnaty covid vaccine" through October 27, 2021. The Program Surveillance Branch did not locate any BPDRs during that time period for the licensed Comirnaty vaccine. *Id.* (App'x 014).

7. Lot Release Materials and Lot Distribution Reports

The agency additionally searched for submissions related to lot release. Lot release is a system that permits FDA to verify product quality through protocol review and sample testing of biological products. *Id.* ¶ 46 (App'x 014). Under FDA regulations, "[n]o lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product." 21 C.F.R. § 610.1. FDA works with sponsors during the BLA review process to develop lot release protocols (*i.e.*, specific quality testing, agreed upon by FDA) to be used on each lot of products before distribution. Burk Decl. ¶ 46 (App'x 014–015).

Under 21 C.F.R. § 610.2(a), CBER may require manufacturers to submit for CBER review and confirmatory testing samples of any lot of a licensed product, together with the protocols showing results of applicable tests when deemed necessary for the safety, purity, or potency of the product. *See* 21 C.F.R. § 610.2(a). After CBER review, CBER will notify the sponsor whether the lot is "released." *See id.*

Lot release protocols are accessible to agency employees through CBERConnect. Burk Decl. ¶ 47 (App'x 015). The agency searched CBERConnect for lot release protocols associated with STN 125742 and located eleven lot release protocols submitted by Pfizer before the licensure date of August 23, 2021 and two lot release protocols submitted between licensure and October 27, 2021. *Id.* (App'x 015). The agency processed those thirteen lot release protocols in response to Plaintiff's FOIA Request. *Id.* ¶ 48 (App'x 015).

In terms of lot release letters, ALFOI was initially aware of seven responsive lot release letters that had been publicly posted to FDA's website in response to prior FOIA requests. *Id.* ¶ 49 (App'x 015). To ensure that it processed all responsive lot release letters, ALFOI also contacted CBER's Product Release Branch in its Division of Manufacturing and Product Quality, asking for "any associated Lot Release Letters for the product Comirnaty" through October 27, 2021. *Id.* ¶ 50 (App'x 015). The Product Release Branch provided ALFOI with two letters within the relevant date range (*i.e.*, prior to October 27, 2021), and ALFOI determined that they too were already accessible on FDA's website. *Id.* (App'x 015). Because these records were already publicly available, the agency did not reprocess those records, but the agency alerted Plaintiff's counsel to their availability on FDA's website in its November 1, 2023 production cover letter, and provided courtesy copies of them in the November 1, 2023 production. *Id.* (App'x 015–016).

In order to locate records reflecting CBER's testing of lots for the original Comirnaty

vaccine licensure, ALFOI contacted CBER's Division of Biological Standards and Quality Control asking for "any possible CBER Testing records related to the product Comirnaty (STN 125742)[;] . . . these would be records where CBER conducted the tests on the product." *Id.* ¶ 51 (App'x 016). The Division's Quality Assurance Branch responded by providing ALFOI with five testing review memos for lots within the relevant date range (*i.e.*, before October 27, 2021). *Id.* (App'x 016). ALFOI determined that two of the five records were duplicative of records it had identified in its search for FDA-generated records related to the BLA, and it processed the other three testing review memos in response to Plaintiff's FOIA Request. *Id.* (App'x 016).

Finally, the agency determined that it did not need to search for lot distribution reports, which reflect information about the quantity of product distributed under a license in the timeframe covered by the report, because an FDA-generated record related to the BLA (which the agency processed in response to Plaintiff's FOIA Request) reflected that Pfizer had requested, and FDA had approved, a waiver allowing Pfizer's first report to be filed in January 2022 (*i.e.*, after the October 27, 2021 search cut-off date). *Id.* ¶ 52 (App'x 016). Still, to ensure its interpretation of the FDA-generated record was accurate, ALFOI shared the FDA-generated record with CBER's Division of Pharmacovigilance in its Office of Biostatistics and Pharmacovigilance, who confirmed it "[did] not have a lot distribution reports [*sic*] submitted for STN 125742 prior to 10/27/2021." *Id.* ¶ 52 (App'x 016).[7]

* * *

As detailed above and in the accompanying Burk declaration, FDA worked diligently to

[7] While this brief and the agency's declaration discuss the records the agency processed in certain categories for ease of reading and organization, *see supra* Part IV.B, some records fall under more than one of the above-discussed categories. For example, drug master files are discussed separately, but they would, of course, also be records incorporated by reference in the BLA.

conduct a good faith search that was reasonably calculated to uncover all responsive records. Defendant thereby complied with its obligations under FOIA. *See Weisberg*, 705 F.2d at 1351; *Batton*, 598 F.3d at 176. Accordingly, Defendant is entitled to summary judgment with respect to the adequacy of the search.

V. CONCLUSION

For the foregoing reasons, the Court should grant Defendant's motion for summary judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2024, I electronically filed this document with the Clerk of the Court for the United States District Court for the Northern District of Texas by using the CM/ECF system. Counsel in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

/s/ Andrew F. Freidah
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